

REMARKS

Reconsideration is respectfully requested in view of the following remarks.

The Examiner has withdrawn the rejections of the Office Action mailed November 4, 2003 in view of the lack of unity requirement dated July 22, 2004.

Response to Lack of Unity Requirement

In the action dated July 22, 2004, the Examiner states that unity of invention is considered to be lacking. The Examiner alleges that the claims fall into thirty-three groups. Groups I – V are directed to compounds, while Groups VI – XXXIII are directed to methods.

Applicants respectfully traverse the lack of unity requirement. Specifically, the Examiner fails to satisfy the requirements for lack of unity for Groups I-V directed to compounds, and fails to satisfy the requirements for lack of unity for Group VI-XXXIII directed to methods. The Examiner improperly applies the lack of unity criteria to compound claims having Markush groups, and improperly interprets the rules relating to unity of invention with respect to method groups.

Treatment of Unity of Invention for Markush Group Claims

The claims of Groups I-V are directed to a compound containing Markush groups. As addressed by Applicants in the response dated May 4, 2004 and reiterated here, the correct standard for unity of invention for Markush type claims is set forth in MPEP 1850, subsection D, which states that

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity;
and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

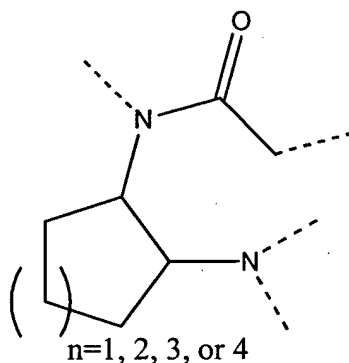
(C) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Regarding the meaning of a “significant structural element” as used in section (B)(1) above, MPEP 1850, subsection D1 states that this refers to two cases: (1) where the compounds share a common chemical structure which occupies a large portion of their structures, or (2) in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. Appendix AI, Annex B, Part 2 III of the MPEP sets forth examples of Markush claims for which unity of invention is present and is not present.

Under the standard set forth above, a Markush claim possesses unity of invention unless the compounds within the Markush group either (1) do not share a common utility, or (2) do not share a significant common structural element or belong to a recognized class of chemical compounds.

First, as described in the specification, the compounds of the Markush group set forth in claim 1 may be used in pharmaceutical compositions for the treatment of conditions including but not limited to arrhythmia. The compounds within the Markush group therefore share a common utility.

Second, the compounds share a common structural element, by virtue of which they belong to a recognized class of chemical compounds. The compounds of the Markush group are all 2-amino cycloalkyl amides. That is, all compounds in the group share the common structural element shown below, where ---- indicates that the valency is filled with a substituent as defined in claim 1.



This molecular compound is a significant structural element in the molecules set forth in the Markush group. That is, the common structural element occupies a large portion of the compounds' structure. Because the compounds in the claim 1 Markush group possess a common utility and share a significant common structural element, unity of invention is present.

Furthermore, there is no support provided in Appendix AI, Annex B, Part 2 III of the MPEP, which sets forth examples of Markush claims in which unity of invention is present and is not present. Instead, the Markush group of pending claim 1 corresponds to examples provided by the MPEP that have a common structural feature. As in claim 1 of the present case, Examples 18-21 in the MPEP show a series of compounds having a common central structure with various substituent groups. In addition, all the compounds have the same use. Like the examples, claim 1 is directed to a compound having common structural features and the same use. Example 23, by contrast, specifically depicts a Markush group having no common structure. The components of the Example 23 Markush group are inorganic salts, organic salts and carboxylic acids, amides, nitriles, phenols, amines, and heterocycles. Unlike Example 23, the Markush group of claim 1 in the present application includes substituents having common structural features such as those of Examples 18-21. Unity of invention is therefore present.

Applicants also note that the PCT examiner, applying the above described standards for determination of unity of invention, did not reject claim 1 for lack of unity of invention.

Examiner's Arguments

The Examiner incorrectly alleges that the compounds defined in the claims “lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art as can be seen by formula I in column 2 of US Patent No. 5,506,257.” (emphasis added). The analysis advanced by the Examiner only applies “in case the compounds have in common only a small portion of their structures.” In the present case, the 2-amino cycloalkyl amide moiety is a significant structural element of the claims, as discussed above.

Further, with respect to contributions over the prior art, the Examiner must consider the invention as a whole. Applicants note that the standard for unity of invention is recited in 37 C.F.R. 1.475 (and in PCT rule 13.1 and 13.2 as cited by the Examiner). Therein, it is stated that:

“unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art (emphasis added).”

Applicants note that it is not required by 37 C.F.R. 1.475 that the “special technical feature” define a contribution over the prior art, but rather that the claimed invention, considered as a whole, define a contribution over the prior art. The presently claimed invention, considered as a whole, is free of the prior art.

Method Claims

Groups VI-XXXIII are directed to methods of using the compound of claim 1.

The Examiner alleges at pages 14-15 of the Office Action that “even if unity of invention under 37 CFR 1.475(a) is not considered to be lacking, ...under 37 CFR 1.475(b) a national stage application containing claims to different categories of the invention will be considered to have

unity of invention if the claims are drawn only to one” of certain categories of claim type combinations. The Examiner further states that “according to 37 CFR 1.475(c) if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.” (emphasis added). The Examiner concludes that the claims lack unity and should be limited only to a product or method of use.

The Examiner misapplies the requirements of 37 CFR 1.475. 37 CFR 1.475(b) does not apply to the pending claims. Rather, 37 CFR 1.475(b) only applies to the instance in which all claims are directed to a one of the categories of claims delineated in 37 CFR 1.475(b). In the present case, the claims are not directed to a single delineated category of claims, so 37 CFR 1.475(b) does not apply. Applicants also note that 37 CFR 1.475(b) only addresses instances in which claims are drawn to one of the specified categories, not instances in which claims are not directed to one of the specified categories.

37 CFR 1.475(c) applies to cases in which an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b). In such cases, “unity of invention might not be present” (emphasis added). The language of 37 CFR 1.475(c) does not require that unity of invention not be present, however.

The correct provision for the method claims is 37 CFR 1.475(a). 37 CFR 1.475(a), “the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.” (emphasis added). In the present the claimed invention is the novel compounds of claim 1. Further, even if the Examiner were correct that the compound claims of claim 1 lack unity of invention, the compound claims and method claims all share a “special technical feature” (i.e. the patentable compound of claim 1).

Groups VI-XXXIII therefore fail to satisfy the requirements for lack of unity, as alleged by the Examiner.

In view of the foregoing, Applicants respectfully request that the lack of unity determination be withdrawn.

In the event that the instant lack of unity requirement is maintained despite the above discussion, Applicants hereby elect Group II with traverse for the reasons presented above.

CONCLUSION

Applicants believe that the present application is in condition for allowance.

In the event that there are any questions, comments, or suggestions concerning this amendment or the application in general, or if an interview is considered desirable, the Examiner is requested to telephone the undersigned representative so that prosecution may be expedited.

In the unlikely event that the Patent Office determines that an extension and/or other relief is required as a result of this statement, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due to our **Deposit account no. 03-1952** referenced Docket No. 554792000800. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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